UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.Ph.

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Defendants' Executive Committee, on behalf of the undersigned Defendants, respectfully submits this Memorandum of Law in Support of Defendants' Joint Motion to Exclude or Limit the Opinions of Dr. Kaliopi Panagos pursuant to Federal Rules of Evidence 104, 403, 702, and 703 ("Motion").

INTRODUCTION

In support of class certification of Third-Party Payor Claims, Plaintiffs seek to offer testimony from Kaliopi Panagos, Pharm.D., R.Ph. that the third-party payor Plaintiffs (TPPs) should not have reimbursed consumer prescription costs for the valsartan containing drugs (VCDs) at issue in this litigation.[1]

Dr. Panagos, a pharmacist and consultant in the managed care and pharmacy fields, opines that a generic drug listing and rating in the FDA publication called Approved Drug Products with Therapeutic Equivalence Evaluations (commonly called the "Orange Book") purportedly serves as a manufacturer's "warranty" to TPPs that the drug is bioequivalent to the reference listed drug (the "RLD," also often referred to as the branded drug). She further opines that because these VCDs allegedly contained "contaminants" that were not in the RLD, the bioequivalence was nullified and the purported "warranty" rendered false. She goes on to opine that,

[1] A copy of Dr. Panagos's Expert Report (hereinafter, "Report"), is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit A**.

because of this, the VCDs should not have been placed on drug formularies and TPPs should not have paid for the products.

Dr. Panagos's opinions are prototypical examples of the sort of unreliable, unqualified, and unhelpful expert opinions subject to exclusion under Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

***First*, Dr. Panagos's opinions are unreliable.** Most fundamentally, Dr. Panagos utterly failed to identify the specific bases of any of her opinions, whether in her brief 11-page report or in her deposition testimony. In particular, although Dr. Panagos seeks to opine that generic valsartan is not bioequivalent to the RLD for purposes of its inclusion in the FDA-published Orange Book, she does not identify any regulatory standards, literature, or data supporting this claim, presumably because she has no pertinent professional and/or educational experience with the FDA, nitrosamines, valsartan, or bioequivalence. The same is true with respect to Dr. Panagos's opinions that the FDA's approval of generic valsartan qualifies as a "warranty" of bioequivalence by the manufacturer and that the presence of purported contaminants constitutes a breach of such an alleged warranty. After all, Dr. Panagos does not ground these opinions—which, as explained further below, are regulatory and legal conclusions rather than appropriate expert opinions—in any objective regulatory standard, much less explain how the NDMA/NDEA "contaminants" might change the bioequivalence profile or bear on the FDA's decision to include

generic valsartan in the Orange Book. Instead, Dr. Panagos relies solely on her own *ipse dixit*. Indeed, when pressed at her deposition for the bases for her specific individual conclusions, Dr. Panagos generically pointed to her reliance list, insisting every item on that list supported each unique opinion (several times needing to walk back this illogical assertion upon being confronted with references that clearly did not support a particular opinion). In short, Dr. Panagos's Report and testimony lay bare that her opinions are not based on ***any*** methodology, much less a reliable one.

Second, **Dr. Panagos is not qualified to opine on the topics in her Report.** She has never worked for or consulted with the FDA, nor has she worked as a consultant with respect to the regulatory processes applicable to pharmaceutical products (indeed, she has never done any work at all for pharmaceutical companies). She has done no professional work (nor authored any publications) regarding nitrosamines, valsartan, bioequivalence, or other FDA regulatory issues. She has never been an employee of a TPP or a member of a Pharmaceutical and Therapeutics Committee ("P&T Committee").[2] Plaintiffs have failed to show that Dr. Panagos has the necessary specialized knowledge regarding her areas of testimony.

[2] P&T committees "help determine which drugs will be included in a drug formulary." Certificate in Formulary Drug Evaluation Processes, UW-Madison School of Pharmacy, https://ce.pharmacy.wisc.edu/pd/formulary_drug_evaluation_processes/ (last visited Apr. 25, 2022).

***Third*, Dr. Panagos's FDA-related opinions are improper regulatory and legal conclusions,** and therefore are not appropriate expert testimony. Courts have routinely made clear that an expert may not usurp the role of the jury by offering legal conclusions that a manufacturer did not comply with FDA requirements. But that is exactly what Dr. Panagos seeks to do in this case by not only interpreting the legal requirements for FDA approval of a drug, but also speculating on whether Defendants complied with their supposed obligations. That is plainly improper and separately warrants exclusion of Dr. Panagos's FDA-related opinions.

***Fourth*, Dr. Panagos's opinions will not assist the factfinder and do not "fit" this case.** Dr. Panagos relies wholly on information found within the Complaint for proof that any TPP sought a refund after paying for a nitrosamine-containing VCD. Additionally, her FDA-related opinions are based *not* on any FDA definitions or guidance, but instead on her own subjective definitions of words like "bioequivalence" and "warranty." This will likely confuse or mislead the factfinders instead of helping them. And, while Dr. Panagos seeks to opine on payments that the TPPs allegedly should not have made due to the purportedly "contaminated" nature of the VCDs, Dr. Panagos failed to identify from any source other than the Complaint any TPPs that removed or blocked VCDs from their formularies following the recalls, or that actually paid for a "contaminated" VCD and/or sought

a refund after making such payment. Without this information, her opinions do not "fit" the facts of this case and would be of no use to the trier of fact.

Thus, and as explained in more detail below, Plaintiffs have failed to demonstrate the admissibility of any of Dr. Panagos's opinions, warranting their exclusion.[3]

BACKGROUND

Plaintiffs' proffered expert, Kaliopi Panagos, Pharm.D., R.Ph., was retained by Plaintiffs' counsel "to render an opinion regarding what information [TPPs] rely on and consider with respect to generic drugs and, more specifically, the Valsartan and Valsartan Containing Drugs at issue in this litigation." (Report ¶ 1.) In essence, Dr. Panagos—a pharmacist and consultant in the managed care and pharmacy field who has never worked with or for the FDA, for a pharmaceutical manufacturer, or for a TPP—opines that:[4]

- a generic drug listing and rating in the Orange Book (which is an official FDA publication) purportedly serves as some sort of "warranty" by the manufacturer to

[3] Defendants reserve the right to move to exclude or limit Dr. Panagos's opinions on grounds other than those set forth herein if those grounds become available after the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in this case, or supplementation of Dr. Panagos's disclosure or Report.

[4] (*See* Report ¶¶ 5, 7; Transcript of January 21, 2022 deposition of Kaliopi Panagos ("Panagos Dep.") 42:18–19, 65:20–21, 79:3–5, attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit B**.)

TPPs that the drug is bioequivalent to the RLD (*id*. ¶¶ 47, 51, 55);

- these VCDs allegedly contained "contaminants" not in the RLD, so "bioequivalence" was purportedly nullified and the purported "warranty" was false (*id*. ¶ 59; *id*. §§ VI.I–J);
- "TPPs and P&T committees *expressly* rely upon the manufacturer's compliance with all applicable standards, obligations, and regulations" when considering generic drugs for placement on a formulary (*id*. ¶ 46 (emphasis added));
- "TPPs reimbursed for these VCDs based on the warranty provided by the manufacturer and [Pharmacy Benefit Managers ("PBMs")] establish formularies of bioequivalence based on the FDA approval process and information within the Orange Book" (*id*. § VI.H); and
- Because the purported "warranty" was false, TPPs "unjustly" paid for medications for which they should not have paid (*id*. §§ VI.I–J).

Notably, Dr. Panagos testified that she rendered her opinions using her own subjective definition for the term "warranty." (Panagos Dep. 123:2–7 ("Q. When you use the term warranty in your report, do you understand that to be a legal term? . . . A. No. It's a term that refers to a promise, an assurance, a guarantee that that manufacturer has set forth.").)

Dr. Panagos also does not know the FDA definition of bioequivalence (*see,*

e.g., *id*. at 176:6–179:12).[5] She testified that she was not asked to study the FDA's definition of bioequivalence for her Report and "did not review" whether the Code of Federal Regulations contains the FDA's definition of bioequivalence. (*Id*. at 115:10–13, 176:6–12.)

Instead, Dr. Panagos rendered her opinions using her *own subjective* definition of "bioequivalence." (*See, e.g.*, *id*. at 177:23–178:5 ("I believe my definition in my report captures what a bioequivalent drug product -- captures the definition appropriately.").) Moreover, she did not review any bioequivalence studies for any products at issue in this litigation. (*Id*. at 151:4–7.) She has never published on the topic of bioequivalence and, to the best of her recollection, has never taken a course dedicated to the subject. (*Id*. at 52:15–17, 56:2–6.) Nor has she "published any articles relating to the FDA regulatory requirements that apply to pharmaceutical products," "worked or consulted with FDA," "done consulting work for any pharmaceutical company," or had "any personal experience with the

[5] A generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient "do not show a significant difference" from those of the brand drug. 21 U.S.C. § 355(j)(8)(B)(i).

manufacturing of pharmaceutical products." (*Id*. at 52:18–21, 65:20–21, 79:3–5, 172:22–24.) She also has never been employed by a TPP. (*Id*. at 42:18–19.)

ARGUMENT

The standards governing the admissibility of expert opinions at the class certification stage of litigation are set forth in Defendants' motion to exclude the opinions of Dr. Edward Kaplan. (*See* Defs.' Mot. to Exclude Ops. of Dr. Edward H. Kaplan, M.D. [Dkt. No. 2024-1] at 6–9.) As explained below, Dr. Panagos's opinions do not satisfy those standards for multiple reasons.

I. DR. PANAGOS COULD NOT IDENTIFY ANY SUPPORT FOR HER OPINIONS.

The Court should exclude Dr. Panagos's opinions first and foremost because they are not based on any methodology, as reflected by her utter failure to identify the bases supporting her various opinions. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Instead, "experts must explain precisely how they went about reaching their conclusions and point to some objective source . . . to show that they have followed the scientific method . . . ." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995); *see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 835 (3d Cir. 2020) (holding expert testimony unreliable and "unsupported by 'good grounds'" where the expert

"presented no quantifiable data to explain or clarify his assumptions"); *Diviero v. Uniroyal Goodrich Tire Co.*, 114 F.3d 851, 853 (9th Cir. 1997) (concluding that expert testimony was unreliable where expert was unable "to explain the reasoning behind his opinions"). In other words, "[w]ithout more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987).[6]

Here, Dr. Panagos has offered only her subjective say-so, not a discernible methodology, much less a methodology that meets the dictates of Rule 702. Dr. Panagos's Report does not identify which particular reference(s) support her individual opinions (e.g., by providing footnotes or textual citations identifying specific references for the individual numbered paragraphs in her Report). And when asked for the bases at her deposition, Dr. Panagos was likewise unable to identify the support for her various opinions. Instead, she kept insisting that every individual opinion was based on *every single item* in the appendix to her Report. (Panagos Dep. 99:1–13, 99:17–21.)[7] Vaguely pointing counsel to an index of documents does not suffice, as "experts must explain precisely how they went about reaching their

[6] As explained *infra* in Sections II.B., III.B., IV.C., Dr. Panagos does not even have credentials to lend support to her subjective opinion testimony.

[7] In fact, this line of questioning prompted Plaintiffs' counsel to (unsuccessfully) request a stipulation that Dr. Panagos's "testimony about what she's relied on for her entire report . . . apply to each question about what she relied on for a particular paragraph." (Panagos Dep. 111:7–13.)

conclusions and point to some objective source . . . to show that they have followed the scientific method." *Daubert*, 43 F.3d at 1319. This fundamental flaw permeated her testimony with respect to each and every asserted opinion and warrants its exclusion.

This is especially so because, on several occasions, after repeating her blanket reliance mantra, Dr. Panagos reluctantly conceded when pressed that she, in fact, did *not* rely on certain items in her reliance list that could not possibly have supported the opinion she was asked about. (*See, e.g.*, *id*. at 108:1–109:6, 113:7–114:19.) For other opinions, Dr. Panagos simply failed to offer any basis at all, providing instead unresponsive, evasive answers. For example, when asked to identify a document "in which a P&T committee **expressly** relies upon the manufacturer's compliance with all applicable standards, obligations, and regulations," Dr. Panagos responded with the following *non-sequitur*: "The Orange Book is a representation of a list of drugs approved safe and effective for use in the United States." (*Id.* at 120:19–121:1.)

Dr. Panagos's Report and testimony leave no doubt that her opinions run afoul of the basic requirement that expert testimony be "based on the methods and procedures of science, not on subjective belief and unsupported speculation." *UGI Sunbury LLC*, 949 F.3d at 833–34. Therefore, and for the individual reasons discussed below, her opinions should be excluded in their entirety.

II. DR. PANAGOS'S FDA-RELATED OPINIONS REGARDING BIOEQUIVALENCE, FDA APPROVAL, AND ADDITION OF A DRUG TO THE ORANGE BOOK SHOULD BE EXCLUDED.

Dr. Panagos opines that TPPs reimbursed for the VCDs at issue because they were included in the FDA's Orange Book after receiving FDA approval (which turns, in part, on Defendants' showing of bioequivalence with the RLD). She further opines that:

- "If the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication; equivalence is nulled and the generic manufacturer may no longer rely on the brand name drug label." (Report § VI.D)
- "The presence of the contaminant rendered the manufacturer defendants' versions of VCDs **not** equivalent to the branded product as indicated in the Orange Book which serves as the source of truth for bioequivalence."[8] (*Id*. ¶ 59.) Dr. Panagos asserts without any basis whatsoever that the "contaminants"—NDEA and NDMA (Panagos Dep. at 141:18–21)—"were not in the branded product and therefore

[8] The Orange Book "identifies drug products approved on the basis of safety and effectiveness by the [FDA] . . . ." Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book (Apr. 8, 2022), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

> the generic drug could not have been equivalent to the branded product by the presence of the contaminants within the product, within the medication" (*id*. at 142:3–6).

These "speculative [regulatory opinions] do not demonstrate the level of 'intellectual rigor' envisioned by *Daubert*" and should be excluded. *Rhodes v. Bayer Healthcare Pharms., Inc.*, No. 10-1695, 2013 U.S. Dist. LEXIS 44670, at *22–23 (W.D. La. Mar. 26, 2013); *see also id*. at *22 (holding that an "opinion regarding Avelox's labeling is not based on sufficient evidence and is not a product of a reliable methodology" where pharmacist "either did not explain how he reached such conclusions, *i.e.*, 'I can give you some things off the top of the head,' or he explained his conclusions as a 'rough guesstimate'"). Dr. Panagos does not point to any data, studies, or other objective material to support her assumption that the VCDs and the branded drug were no longer bioequivalent, or even that they differed from each other with respect to presence and amount of nitrosamines. Nor does she offer any basis for her opinions regarding the requirements for obtaining the FDA's approval of a drug (including, specifically, that VCDs "would not have been approved with the contaminant" (Panagos Dep. 147:5–6)), drug manufacturers' responsibilities in that regard, and how manufacturers might lose that FDA approval. Dr. Panagos further has no basis to opine on the FDA's decision to include a generic drug in the Orange Book.

Nor can she demonstrate that she is qualified to give these regulatory opinions, i.e., that she has an expert-level understanding of the "bioequivalence" concept, FDA approval, or the FDA's decision to include a drug in the Orange Book. *See, e.g.*, *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 773 (S.D. Ohio 2015) (neurologist "not qualified to opine on the regulatory aspects of the case"); *In re Trasylol Prods. Liab. Litig.*, No. 08-CV-81230, 2011 WL 7109297, at *6 (S.D. Fla. Apr. 27, 2011) (anesthesiologist "not qualified to opine on" "FDA regulations and labeling"). In fact, she is squarely prohibited from offering her purported regulatory conclusions, which are not the proper subject of expert testimony. Finally, her unsupported bioequivalence opinions will be deeply unhelpful to a factfinder. Accordingly, and as explained further below, the Court should exclude her regulatory opinions relating to bioequivalence, FDA approval, and the purported significance of inclusion in the FDA's Orange Book.

A. Dr. Panagos's Regulatory Opinions Regarding Bioequivalence, FDA Approval, and Inclusion in the Orange Book Lack Support and Are Therefore Unreliable.

None of Dr. Panagos's opinions concerning bioequivalence, FDA approval, and FDA inclusion of a drug in the Orange Book are supported by reliable principles or methods.

1. Dr. Panagos's Bioequivalence Opinions Are Unreliable.

Dr. Panagos purports to offer an opinion on whether generic valsartan is

bioequivalent to the RLD for purposes of its inclusion in the FDA-published Orange Book, but she does not even know the FDA definition of bioequivalence—much less connect it to her opinion. When testifying as to whether the Code of Federal Regulations contains the FDA's definition of bioequivalence, she stated, "I did not review." (Panagos Dep. 176:6–12; *see also id*. at 172:17–21 (explaining that she "[p]ossibly" "read the FDA definition of bioequivalence at [some] point before [she] became retained as an expert in this lawsuit"); *id.* at 115:10–13 (testifying that she "was not asked to study" the FDA regulation defining "bioequivalent" for purposes of her Report). Indeed, *none* of her definitions of "bioequivalent drug products," "bioequivalent," or "bioequivalence" (*see* Report ¶¶ 31, 33, 44) match the definition of "bioequivalence" in the Code of Federal Regulations (21 C.F.R. § 314.3), contrary to her assertion otherwise (Panagos Dep. 177:14–22). One wonders how Dr. Panagos could present an opinion regarding the bioequivalence information in the Orange Book, *an FDA publication*, without even reviewing or familiarizing herself with the FDA's definition of "bioequivalence"—or even considering it to be within the scope of her Report. (*Id*. at 176:13–19.)

Instead, Dr. Panagos rendered her opinions using her *own subjective* definition of "bioequivalence." (*See, e.g.*, *id*. at 177:23–178:5 ("I believe *my* definition in my report captures what a bioequivalent drug product -- captures the

definition appropriately." (emphasis added)). Rule 702 requires more than this type of "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590.

Even assuming Dr. Panagos had any methodology for defining bioequivalence (which she does not), Dr. Panagos would still lack a methodology for opining that Defendants' VCDs failed to meet her subjective definition. Dr. Panagos failed to identify any documents that would support the absence of bioequivalence in Defendants' VCDs, as she had not "review[ed] bioequivalence studies for any manufacturer Defendant's [VCDs]" (Panagos Dep. 151:4–7), and was not aware of any step taken by the FDA (or any other entity) "reflect[ing] a determination that the products were no longer therapeutically equivalent" during or before the timeframe in which they were sold to Plaintiffs (*id*. at 150:7–10, 150:24–151:3).

Nor did Dr. Panagos conduct her own research or analysis of bioequivalence. Plaintiffs' proposed expert did not:

- "read the ANDA for any Valsartan-containing drug" (*id*. at 121:8–10);
- "have any knowledge as to the levels of NDMA or NDEA that were found in any particular lot of [VCDs]" (*id*. at 148:7–14);
- "know whether there were certain lots of recalled Valsartan that did not contain any detectable NDMA or NDEA" (*id*. at 148:16–149:14); or

- evaluate—or even consider within the scope of her Report—"whether the branded product was being tested for" either NDMA or NDEA before the 2018 recall (*id*. at 142:7–21).

In short, Dr. Panagos has no method at all. Her abject failure to review any literature, studies, or data—or to review any information whatsoever—regarding the presence of NDMA or NDEA in the branded product or in VCDs renders her bioequivalence opinions fatally unreliable. *See Ruggiero v. Yamaha Motor Corp*., No. 15-49 (JBS/KMW), 2017 U.S. Dist. LEXIS 48908, at *16–17 (D.N.J. Mar. 31, 2017) (holding an expert opinion was unreliable where the expert, "in developing it, . . . failed to perform any tests" or "rely on any [pertinent] articles . . ., leaving his conclusion to be, at best, an educated guess"), *aff'd*, 778 F. App'x 88 (3d Cir. 2019); *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 789 (3d Cir. 2009) (concluding that an expert's opinion was not reliable in part due to the lack of "outside documentary evidence . . . supporting his conclusions").

2. Dr. Panagos's FDA Approval and Orange Book Opinions Are Unreliable.

As with all of her opinions, Dr. Panagos offers her FDA-related approval and Orange Book inclusion opinions without identifying any support for them. For instance, Dr. Panagos failed to identify a regulation supporting her statement that manufacturers must "understand[] their processes which includes preventing the presence of unacceptable and impurities" [*sic*] (Report ¶ 52), repeatedly testifying

instead that the basis for that opinion was solely that "[m]anufacturers are the ones submitting their application requesting approval" and, therefore, are responsible for the information therein (Panagos Dep. 130:9-16, 131:9-132:8). Indeed, Dr. Panagos *admitted* that the opinion is simply her own subjective belief:

> A. The information presented to the FDA for approval by an ANDA application is presented by the manufacturer who is responsible for the information they provide.
> . . .
> Q. And what is your answer based on?
> . . .
> A. The application is submitted by the manufacturer who is responsible for the information they provide the FDA to be considered for approval. That includes all aspects related to that application.
> . . .
> Q. What is your support for that response?
> . . .
> A. Manufacturers are responsible for their medication. They're responsible for the quality control, ensuring that that medication is safe and effective to -- when they're applying for that approval -- seeking approval by the FDA. It's their responsibility to ensure that it's safe and effective.
> . . .
> Q. Is that your own opinion?
> . . .
> A. In my professional capacity, that is what I believe to be correct.

(*Id*. at 116:25–117:23; *Daubert*, 509 U.S. at 590 (requiring "more than subjective belief"); *Yazujian v. PetSmart*, 729 F. App'x 213, 215–16 (3d Cir. 2018) (excluding expert testimony that "constituted no more than 'subjective belief or unsupported speculation'") (citation omitted); *see also Joiner*, 522 U.S. at 146 (explaining that a

court need not accept "*ipse dixit* of the expert").[9] The glaring lack of support for Dr. Panagos's FDA-related opinions warrants their exclusion as unreliable.

B. Dr. Panagos Lacks Expertise Regarding Bioequivalence, FDA Approval, and Inclusion in the FDA's Orange Book.

Dr. Panagos has no qualifications related to bioequivalence and therefore is wholly unqualified to opine as to the definition of bioequivalence and whether Defendants' VCDs met that definition at the time they were sold to Plaintiffs. She has never published on the topic of bioequivalence and, to the best of her recollection, has never taken a course dedicated to the subject. (Panagos Dep. 52:15–17, 56:2–6.) Nor has she "published any articles relating to the FDA regulatory requirements that apply to pharmaceutical products," "worked or consulted with FDA," "done consulting work for any pharmaceutical company," or had "any personal experience with the manufacturing of pharmaceutical products." (*Id*. at 52:18–21, 65:20–21, 79:3–5, 172:22–24.) Plaintiffs have utterly failed to meet their burden to show Dr. Panagos is in any way qualified to render an opinion on bioequivalence.

Additionally, Dr. Panagos is not qualified to offer her opinions regarding FDA approval or the purported implications of a drug's inclusion in the Orange Book, as

[9] Any attempt by Dr. Panagos to invoke her professional experience or purported "expertise" to bolster this subjective belief is ineffective, given that she is entirely unqualified to render any FDA-related opinions. *See infra* subsection B.

she has not, among other things, published any articles on either topic, consulted with the FDA or any pharmaceutical company, or had experience with pharmaceutical manufacturing. (*Id*. at 52:18–21, 56:16–17, 65:20–21, 79:3–5, 172:22–24.) She simply lacks the requisite "specialized expertise" needed to provide her FDA regulatory opinions. *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 231 (3d Cir. 2003) (citation omitted).[10]

Indeed, despite opining that VCDs would not have been approved with the presence of NDMA or NDEA, Dr. Panagos testified that she will not "offer any opinions on the process for obtaining approvals from FDA for generic pharmaceutical products." (Panagos Dep. 75:11–77:5.) And when asked whether she "hold[s] [herself] out as an expert on the process for approval of pharmaceutical products by the FDA," Dr. Panagos testified only that she "understand[s] what the process entails." (*Id*. at 66:3–6.) That evasive response does not indicate that she has any more understanding of the FDA-approval process than what a layperson could glean from a Google search.

[10] An expert's lack of qualifications is also a "reliability" consideration under Rule 702. *See Calhoun*, 350 F.3d at 321. Dr. Panagos's lack of expertise on these topics further indicates the unreliability of her bioequivalence, FDA approval, and Orange Book opinions. This similarly applies to Dr. Panagos's opinions concerning warranties, the factors considered by TPPs and/or P&T committees when placing, or reimbursing for, a drug on a formulary, and nitrosamines. *See infra* Sections III.B. and IV.C. & n.21.

Similarly, Dr. Panagos lacks the specialized knowledge and expertise to offer her purported opinions on FDA's decisions on therapeutic equivalence evaluations and ratings in the Orange Book, which are subject to complex and non-static scientific evaluations by the FDA. *See Abbott Labs. v. Mylan Pharms., Inc.*, 15 So. 3d 642, 656 (Fla. Ct. App. 2009) (referencing "the complex science which the FDA uses to develop the list of generic drugs included in the Orange Book" and the "not static" "scientific methodology applied by the FDA in approving drug products for inclusion in editions of the Orange Book"); *see also* Orange Book Preface (42nd Edition) (Jan. 19, 2022), *available at* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface ("Orange Book Preface") ("The therapeutic equivalence evaluations in the Orange Book reflect FDA's application of specific criteria to the multisource prescription drug products listed in the Orange Book and approved under Section 505 of the FD&C Act."). Plaintiffs have not established that Dr. Panagos is qualified in any way to provide expert opinion on such evaluations.

Accordingly, these opinions should be excluded based on Dr. Panagos's lack of qualifications.

C. Dr. Panagos's Bioequivalence, FDA Approval, and Orange Book Opinions Are Impermissible Regulatory Conclusions That Will Not Assist the Factfinder.

As an expert witness, Dr. Panagos may not offer legal or regulatory opinions. *See Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). Although experts "may sometimes testify on the specific issue of how a government agency applies and enforces its regulations in the context of a complex regulatory regime," *Moorestown Twp. Bd. of Educ. v. S.D.*, No. 10-0312, 2010 U.S. Dist. LEXIS 109856, at *13 (D.N.J. Oct. 15, 2010), they may not offer their own opinions on a pharmaceutical company's compliance with applicable regulations, *see, e.g.*, *Stanley v. Novartis Pharms. Corp.*, No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014) (precluding an expert from "offer[ing] legal conclusions, including whether Defendant was in regulatory compliance with the FDA"); *see also In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016) (excluding an expert opinion as to whether a drug met a certain standard pursuant to FDA regulations, as such "would require a legal interpretation" of that standard); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding "the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert"); *cf. United States v. Xue*, No. 18-122, 2022 U.S. Dist. LEXIS

63766, at *34–35 (E.D. Pa. Apr. 6, 2022) (precluding experts' use of the term "trade secret" as it "is a term of art with specialized legal meaning, especially in [a] case" where "trade secret" is statutorily defined and "an element of the offenses charged"). Furthermore, "[i]t is well-settled that matters of statutory construction are not a proper subject for expert testimony, but rather, questions of law to be resolved by the Court." *Moorestown Twp. Bd. of Educ.*, 2010 U.S. Dist. LEXIS 109856, at *12–13.

Here, Plaintiffs seek to offer Dr. Panagos's testimony as to Defendants' regulatory compliance as it relates to bioequivalence (i.e., whether the generic drugs were bioequivalent to the branded drug), a term "with specialized legal meaning" in this case.[11] *Xue*, 2022 U.S. Dist. LEXIS 63766, at *34–35. They also seek to offer

[11] Moreover, Dr. Panagos's opinions concerning the term "bioequivalence"—which are based not on any FDA regulation, but her own *personal* and unqualified understanding of the concept—would serve only to confuse or mislead (and not to *help*) the trier of fact when determining whether the VCDs were bioequivalent for purposes of inclusion in the FDA's Orange Book. *UGI Sunbury LLC*, 949 F.3d at 835 (explaining that expert testimony must "help the trier of fact to understand the evidence or to determine a fact in issue") (citing Fed. R. Evid. 702(a)). Exclusion of these opinions is also warranted under Rule 403 given the risk that Dr. Panagos will mislead the factfinder using words with intended meanings other than those used by other experts. Fed. R. Evid. 403; *United States v. Williams*, 974 F.3d 320, 358 (3d Cir. 2020) ("It is well established that a district judge has a 'general gatekeeping obligation' with respect to all testimony based on specialized knowledge of some form. Under Federal Rule of Evidence 702, she must ensure that such testimony is both reliable and relevant, including under the standard laid down in Rule 403." (internal citation and quotation marks omitted)); *Xue*, 2022 U.S. Dist. LEXIS 63766, at *35–36 (precluding, under Rule 403, "expert witnesses from using the [legal] term [of art] 'trade secret'" due to the risk of undue prejudice).

her regulatory opinions about the requirements for, and significance of, FDA approval of a drug; whether Defendants complied with those regulations; and the FDA's regulatory process with respect to the Orange Book. Black letter law precludes Plaintiffs from doing so.

III. DR. PANAGOS'S OPINIONS REGARDING DEFENDANTS' ALLEGED "WARRANTY" SHOULD BE EXCLUDED.

Dr. Panagos asserts that the FDA's approval of a drug, or the FDA's subsequent inclusion or rating of the drug in the Orange Book, serves as some sort of "warranty" by the manufacturer, and that such warranties by Defendants were false. (*See* Panagos Dep. 123:9–14, 126:15–19; *see also* Report ¶¶ 47, 55, § VI.A–B, I–J.) Dr. Panagos has no reliable basis for these "warranty" opinions and is wholly unqualified to opine on this topic.

A. Dr. Panagos's Opinions Concerning the Existence and Veracity of an Alleged "Warranty" Are Unsupported.

Dr. Panagos does not, because she cannot, point to any valid support for her warranty opinions.

First, Dr. Panagos has no basis—other than her own say-so—for her statement that a product's listing in the Orange Book constitutes a "warranty."[12] Confirming

[12] Dr. Panagos admits that the only literature cited in the Report that she thinks supports her conclusions concerning warranties—a report containing guidelines for pharmacists—does not even include the words "warranty," "promise," or "guarantee." (Panagos Dep. 125:14–16, 126:20–23.) Nor does this lone report address or support her specific opinions here that Defendants made any kind of

that she did not use the term "warranty" in its legal sense in the Report (Panagos Dep. 123:2–7), Dr. Panagos's conclusions regarding Defendants' alleged warranties appear premised on her own personal concept of "warranty"—a concept that is neither explained in her Report nor supported by any source to which she can point.[13] Dr. Panagos's continued reliance on her own subjective musings and *ipse dixit* does not pass muster. *UGI Sunbury LLC*, 949 F.3d at 833–34 (stating that an expert opinion cannot be based on subjective belief).

Additionally, Dr. Panagos asserts that Defendants' "warranty" concerning the VCDs was false. (Report § VI.I–J.) The purported basis for Dr. Panagos's opinion is that "[t]he presence of the contaminants in unacceptable levels of probable human carcinogens" rendered false Defendants' purported statements to the FDA "that their drug met the criteria set forth by the FDA for approval." (Panagos Dep. 145:15–25.) Yet Dr. Panagos's "false warranty" opinion depends on her own *personal*

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warranty or that any purported warranty was false. (*See* Christy Ciccarello, PharmD, MHA, et al., *ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System*, 78 Am. J. Health-Syst. Pharm. 907 (2021), attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit C**; *see also Calhoun*, 350 F.3d at 322 (upholding the exclusion of an expert opinion unsupported by any literature or tests).)

[13] Furthermore, exclusion of Dr. Panagos's opinions concerning a purported "warranty"—which are based **solely** on her own personal (i.e., non-expert, *see infra* Section III. B) view of the term—is warranted under both Rule 702's "fit" prong and Rule 403, as they would serve only to confuse or mislead, and not *help*, the trier of fact. *UGI Sunbury LLC*, 949 F.3d at 835; *see supra* n.11; Fed. R. Evid. 403; *Williams*, 974 F.3d at 358.

understanding of the word "contaminants," which is not rooted in any FDA regulation.[14] To the extent Dr. Panagos relies on the statements made by the FDA (in connection with the 2018 voluntary recalls of VCDs) that some VCDs may have exceeded "acceptable" levels of nitrosamines (*see id*. at 145:15–146:23), Dr. Panagos did not examine this statement any further and made no attempt even to determine the time frame during which the purported "warranties" were "false," finding such detail "beyond the scope of [her] report" despite the existence of questions "as to when the original contaminants were there, how long they were

[14] When asked for her understanding of the term "contaminants," Dr. Panagos merely regurgitated Plaintiffs' litigation theme (Panagos Dep. 93:21-23 ("These contaminants were found in unacceptable levels and probable human carcinogens and do not belong in the medication.")) before finally stating: "a contaminant is any substance that is in the medication that should not have been there, not consistent with the referenced label product, and inconsistent with the safety and efficacy of the referenced labeled product" (*id*. at 95:9–13). That definition is not based on any "specific FDA regulation[]," but rather *only* on Dr. Panagos's self-proclaimed "industry knowledge, . . . pharmacy background, . . . education, studies, and professional scope in [her] career." (*Id*. at 95:14–96:2.) Dr. Panagos never explained how her experience purportedly led to or supports her definition of contaminants or why such a definition is appropriate, beyond vaguely asserting that "[t]he scope of [her] career . . . involves referring to FDA information." (*Id*. at 95:22–23.) This is insufficient. *See Ruggiero*, 2017 U.S. Dist. LEXIS 48908, at *14 ("If the witness is relying solely or primarily on experience, . . . [they] must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.") (citation omitted). Dr. Panagos also uses her own personal definition of the term "impurity," not based on any particular FDA regulation or guidance. (Panagos Dep. 129:4–7.) And during her deposition, she testified that she used the terms "impurity" and "contaminants" interchangeably, admitting she did not know "whether FDA views the terms . . . as interchangeable." (*Id*. at 130:1–8.)

there, length of time, and so on." (*Id*. at 136:24–137:24.) Moreover, Dr. Panagos did not know—and considered to be outside the scope of her Report—"the levels of NDMA or NDEA that were found in any particular lot of [VCDs]," "whether there were certain lots of recalled Valsartan that did not contain any detectable NDMA or NDEA," or specifics concerning the FDA's established guidance regarding the control of nitrosamines. (*Id*. at 140:2–8, 148:7–149:14.) And rather than "assess[ing] the carcinogenicity of NDEA or NDMA" herself, she relied solely on the ultimate determination made by the International Agency for Research on Cancer ("IARC"), utterly disregarding the pertinent monographs and underlying studies. (*See id*. at 96:3–24; Report ¶ 12; *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, No. 19-3847, 2021 U.S. Dist. LEXIS 242783, at *13 (E.D. Pa. Dec. 21, 2021) (finding an opinion unreliable in part because the expert did not "independently review the epidemiological research cited by . . . IARC"); *see also Ruggiero*, 2017 U.S. Dist. LEXIS 48908, at *16–17 (excluding an opinion as unreliable where the expert "failed to perform any tests" or "rely on any [pertinent] articles").) How Dr. Panagos could possibly have concluded that Defendants made false statements concerning the VCDs at issue without any of this information or analysis is inexplicable.

In sum, Dr. Panagos has no "good grounds" on which to opine whether the FDA's listing or rating of a drug in the Orange Book represents a warranty by the

manufacturer or whether such a warranty was accurate. Her warranty opinions, which are mere *ipse dixit*, should be excluded as unreliable.

B. Dr. Panagos Has No Qualifications to Render Opinions Concerning an Alleged "Warranty" in the FDA's Orange Book.

The Panagos Report provides that "[t]he 'AB' rating in the FDA Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's warranty to TPPs and P&T Committees for placement on a prescription drug formulary." (Report ¶ 47 (footnote omitted).) But Dr. Panagos lacks any specialized knowledge or expertise to render this opinion. Dr. Panagos has never worked with or for the FDA or published anything on the topic of warranties, and knows no more about the composition of the Orange Book than what can be gleaned from its preface, which is widely available to any internet user.[15] She simply has no qualifications to opine one way or another what does or does not constitute a warranty in this instance.[16]

[15] Moreover, the preface actually refutes Dr. Panagos's opinion regarding Orange Book ratings and manufacturer "warranties." *See, e.g.*, Orange Book Preface ("The main criterion for the inclusion of any product is that the product is the subject of an application with an approval that has not been withdrawn for safety or effectiveness reasons. Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product.").

[16] To the extent Dr. Panagos intends to offer an opinion regarding whether any Defendant *intended* the information submitted to the FDA to constitute a warranty, she is neither qualified to do so, nor permitted to step into the shoes of any Defendant to opine on whether they intended to make a warranty and what that warranty encompassed. *See, e.g.*, *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000

C. Dr. Panagos's "Warranty" Opinions Amount to Impermissible Legal Conclusions.

Finally, whether based on the legal definition of "warranty" or based on her subjective understanding of the term, Dr. Panagos's warranty-related opinions must be excluded as impermissible legal opinions. *See, e.g.*, *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (prohibiting the introduction of expert opinion "about the ultimate legal conclusion or about the law or legal standards"); *Hanreck v. Winnebago Indus.*, No. 1:16-cv-01163, 2019 U.S. Dist. LEXIS 51388, at *56 (M.D. Pa. Mar. 27, 2019) (granting a "motion *in limine* to preclude expert testimony . . . regarding the breach or interpretation of [a] warranty"); *Xue*, 2022 U.S. Dist. LEXIS 63766, at *34–35 (precluding experts' use of the term "trade secret" as it "is a term of art with specialized legal meaning, especially in [a] case" where "trade secret" is statutorily defined and "an element of the offenses charged"); *id.* at *26, 35 (precluding experts' use of "trade secret," even if they "would solely use the term . . . as it is understood in the biopharmaceutical industry," as "the term 'ha[s] a separate, distinct and specialized meaning in the law different from that present in the vernacular'") (alteration in original) (quoting *Torres v. County of Oakland*, 758

U.S. Dist. LEXIS 9037, at *28–30 (E.D. Pa. June 20, 2000) (excluding opinions regarding a drug company's "corporate intent").

F.2d 147, 151 (6th Cir. 1985)).

IV. DR. PANAGOS'S OPINIONS REGARDING DRUG FORMULARIES AND TPPs' PAYMENT OF VCDs SHOULD BE EXCLUDED.

Dr. Panagos has no basis for her ultimate conclusion that, due to a purported false "warranty," the VCDs should not have been included on a drug formulary and should not have been reimbursed by a TPP. Her conclusory opinions lack reliability and should be excluded.

A. Dr. Panagos's Opinions Regarding Whether TPPs Would Have or Should Have Paid for VCDs Are Unsupported and *Ipse Dixit*.

Although retained to render opinions on behalf of "[a]ll TPPs in the United States and its territories and possessions that, since at least January 1, 2012 to the present, paid any amount of money for valsartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant" (Report ¶ 14), Dr. Panagos knew (or revealed) surprisingly little about that class of plaintiffs.

Dr. Panagos evaded questions asking her to identify *any* TPP in the country that removed VCDs from its formulary, sought a refund after paying for an allegedly contaminated VCD, or paid for such a VCD at all. (Panagos Dep. 161:10–15, 161:23–163:8, 163:25–164:11.)

In fact, Dr. Panagos was not willing to discuss TPPs' reactions to the recall at all. Dr. Panagos would not even disclose the *approximate number* of TPPs with which she communicated after the recall (*id*. at 167:9–168:9), let alone their identities or their response to the recall (*id*. at 160:14–19). Dr. Panagos even testified that TPPs had individualized reactions to the 2018 recall for which she did not have any insight and which she *did not consider* when drafting her Report. (*Id*. at 171:8–14, 174:3–12.) Even more egregiously, Dr. Panagos confirmed that she did not even review the strategies (if any) the TPPs *at issue in this case* adopted following the recall, testifying that she was not asked to, and that they were "not within the scope of [her] review." (*Id*. at 190:3–5, 192:2–8.) In other words, despite proffering a blanket statement that TPPs who paid for alleged nitrosamine-containing VCDs were all economically injured, Dr. Panagos did not conduct any research to confirm whether that was true.

Instead, Dr. Panagos proffers an *ipse dixit* opinion regarding TPPs' payment of VCDs, merely repeating her own conclusions when asked to provide the support for those conclusions. (*See, e.g*., *id*. at 163:25–164:5, 164:12–25, 165:2–16.) Such an opinion is not based on any reliable methods or information and, therefore, is not admissible. *See Meadows*, 306 F. App'x at 789 (permitting exclusion of an *ipse dixit* expert opinion). Because Dr. Panagos's conclusion that Defendants' alleged "warranty" concerning the VCDs is false should be excluded, *see supra* Section III,

and because Dr. Panagos lacks any other support for her opinion that the TPPs' payment of the VCDs was inappropriate, this opinion should, likewise, be excluded.

B. Dr. Panagos's Opinions Concerning the Inclusion of VCDs on a Drug Formulary Lack Support.

Dr. Panagos also proffers opinions that VCDs' placement on drug formularies ultimately turns on Defendants' asserted "warranties." (*See, e.g.*, Report ¶¶ 55, § VI.H; Panagos Dep. 119:17–120:1.) These opinions are unsupported by any reliable principles, relying instead on Dr. Panagos's own other opinions, which (as discussed above) are themselves unreliable and excludable.

Dr. Panagos opines: "TPPs reimbursed for these VCDs based on the warranty provided by the manufacturer and PBMs establish formularies of bioequivalence based on the FDA approval process and information within the Orange Book." (Report § VI.H.) The alleged "warranty" Dr. Panagos references throughout her Report and deposition testimony underlies both drugs' inclusion on a formulary and reimbursement. However, for the reasons explained *supra* in Section III, Dr. Panagos' opinions concerning the existence, veracity, and breach of any purported "warranty" should be excluded under Rule 702. Without those underlying opinions, Dr. Panagos lacks any basis at all to argue that the VCDs were improperly included on drug formularies.[17]

[17] Relatedly, Dr. Panagos opines that "TPPs and P&T committees *expressly* rely upon the manufacturer's compliance with all applicable standards, obligations, and

C. Dr. Panagos Is Not Qualified to Offer Opinions Regarding Drug Formularies or Payment of VCDs by TPPs.

Plaintiffs have not established that Dr. Panagos is qualified to opine on the information that P&T committees or TPPs rely on when placing generic drugs on their drug formularies or reimbursing for the cost of prescription drugs.

Dr. Panagos has never been an employee of a TPP or a member of a P&T committee. (Panagos Dep. 42:18-21.) And Dr. Panagos has not established sufficient personal experience with or knowledge of a TPP or P&T committee's decision-making process when it comes to placing a drug on a formulary or reimbursing for its purchase to qualify as an expert. Dr. Panagos testified as to her *general* experience "provid[ing] pharmacy benefit consulting," but any *specific* scope, depth, or frequency of her involvement with creating and managing formularies remains undisclosed.[18] (*Id*. at 36:22–23; *see also id*. at 30:6–10 (explaining that Dr. Panagos

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regulations" when considering generic drugs for placement on a formulary. (Report ¶ 46.) Attempts to elicit the support for that opinion yielded more than four pages in the deposition transcript of unresponsive answers focused on drug manufacturers and Abbreviated New Drug Applications ("ANDAs"), but not one source indicating this "express" reliance. (Panagos Dep. 116:18–121:7.)

[18] Dr. Panagos's brief, ten-month employment where she "set up the pharmacy benefits with regards to formulary" (Panagos Dep. 34:13–35:3) does not qualify her as an expert on the issue. *See Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (collecting cases where an expert was found not qualified due to limited experience, limited familiarity, and/or minimal training in the subject area); *cf*. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*., MDL No. 2445, 2020 U.S. Dist. LEXIS 219949, at *34–36 (E.D. Pa. Nov. 24, 2020) (finding a former, long-time FDA employee with "experience with the specific procedures for filing,

advised "clients on all aspects of their pharmacy program, which *includes* their formulary") (emphasis added); *id*. at 41:3-8 (similar).) She simply has not established that her spotty experience rises to *expert* level. [19]

Finally, Dr. Panagos's wholesale refusal (purportedly due to confidentiality agreements) to identify the name of a single TPP or PBM for whom she has worked fails to establish that she has any relevant experience "provid[ing] consultation or advice concerning inclusion of drugs in a formulary." (*Id*. at 158:23–160:19.) This harms only Plaintiffs themselves, as it is *their* burden to establish their expert's sufficient qualifications. *See, e.g.*, *Wicker v. CONRAIL*, 371 F. Supp. 2d 702, 726 (W.D. Pa. 2005) (disqualifying expert opinions in part because of "the lack of evidence as to qualifications," noting that "[p]roduction of such evidence is the burden of the proponent of the evidence"). They have failed to do so.

D. Dr. Panagos's Opinions Regarding TPPs' Payment of VCDs Will Not Help the Factfinder.

Dr. Panagos's opinions that TPPs paid for medications that they should not have should be excluded, as they will not be helpful to the factfinder. Not only was

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amending, and supplementing ANDAs," who also advised clients on such issues, able to testify meaningfully about the launch of an ANDA product).

[19] Nor is Dr. Panagos qualified to opine on nitrosamines generally, having never published any articles, or even conducted any academic or professional research, regarding nitrosamines. (Panagos Dep. 51:25–52:8.) In any event, Dr. Panagos does not consider the definition of nitrosamines to be "within the scope of [the R]eport or the opinion that [she is] rendering." (*Id*. at 155:19–23.)

Dr. Panagos unable to identify any TPP that paid for, or sought a refund after paying for, a nitrosamine-containing VCD (Panagos Dep. 163:25–164:11), but she also testified that ***the allegations in the Complaint*** were her only basis of knowledge of any "TPP that sought [such] a refund prior to this lawsuit being filed" (*id*. at 165:17–166:2). Because Dr. Panagos's "opinions" merely parrot information within Plaintiffs' pleading, they would not "help the trier of fact to understand the evidence or to determine a fact in issue." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*., MDL No. 2445, 2020 U.S. Dist. LEXIS 219949, at *70–71 (E.D. Pa. Nov. 24, 2020) (citation omitted); *cf*. *Bowers v. NCAA*, 564 F. Supp. 2d 322, 362 (D.N.J. 2008) (excluding an expert opinion as unreliable where, "[i]n support of his conclusion . . ., [the expert] simply quote[d] at length from" a certain document, as "[i]t [wa]s not apparent how [the expert's] parroting of the language in the [document] will contribute to the jury's understanding of" the issue).

Similarly, although the Plaintiff-TPPs' claim depends on whether they paid for VCDs that allegedly contained nitrosamines, Dr. Panagos is admittedly unaware whether the TPPs at issue removed or blocked the recalled VCDs from their formularies (*see* Panagos Dep. 189:23–190:23, 191:3–194:3) or "whether there were certain lots of recalled Valsartan that did *not* contain any detectable NDMA or NDEA," and for which, therefore, payment by the TPPs was not inappropriate (*id*. at 148:16–149:14 (emphasis added)). Accordingly, Dr. Panagos's opinions

regarding the propriety of TPPs' payment for the VCDs are "not sufficiently tied to the facts of this case" and, therefore, do not "fit." *Ruggiero*, 2017 U.S. Dist. LEXIS 48908, at *22–23.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant this Joint Motion to Exclude the Opinions of Dr. Kaliopi Panagos and enter an Order excluding the opinions of Dr. Panagos.

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CERTIFICATE OF SERVICE

I, Kate Wittlake, an attorney, hereby certify that on May 3, 2022, I caused a a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Kate Wittlake
Kate Wittlake